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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/647,156	08/22/2003	Dirk Stenkamp	1/1387	1272

28501 7590 01/14/2008

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EXAMINER	
TRUONG, TAMTHOM NGO	
ART UNIT	PAPER NUMBER
1624	

MAIL DATE	DELIVERY MODE
01/14/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/647,156	STENKAMP ET AL.	
	Examiner	Art Unit	
	Tamthom N. Truong	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *8-29-07 (Election)*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *45-73* is/are pending in the application.

4a) Of the above claim(s) *69-73* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *45-59 and 61-68* is/are rejected.

7)☒ Claim(s) *60* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/10/06 + 6/18/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment of 8-29-07 has been entered and considered. The election of the species in Example 2.1 is acknowledged. The elected species falls within Group I-a, and thus presumed as the elected group as well. Applicant is requested to confirm the elected group in response to this office action.

Claims 1-44 have been cancelled.

Claims 69-73 have been withdrawn.

Claims 45-68 are remained for consideration.

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. **Scope of Enablement:** Claims 62, 65 and 68 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of **obesity**, does not reasonably provide enablement for the treatment and/or prevention of any diseases related to MCH. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The following factors have been considered in the determination of an enabling disclosure:

(1) The breadth of the claims;

(2) The amount of direction or guidance presented;

(3) The state of the prior art;

(4) The relative skill of those in the art;

(5) The predictability or unpredictability of the art;

(6) The quantity of experimentation necessary;

[See ***Ex parte Forman***, 230 USPQ 546 (Bd. Pat. App. & Int., 1986); also ***In re Wands***, 858 F. 2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988)].

The Breadth of the claims: Claim 68 recites "*Method of preventing and/or treating symptoms and/or diseases which are caused by MCH or otherwise casually connected with MCH...*". Said method covers the treatment of diseases such as: obesity, bulimia, bulimia nervosa, cachexia, anorexia nervosa and hyperphagia, diabetes, insulin resistance, encephalorrhagia, cardiac insufficiency, arteriosclerosis, hypertension, arthritis, gonitis, hyperlipidaemia, cellulites, maglinant mastocytosis, emotional disorders, affective disorders, depression, anxiety, sleep disorders, reproductive disorders, sexual disorders, memory disorders, epilepsy, dementia, etc. Many of those have symptoms that contraindicate each other like obesity vs. anorexia, which is encompassed by the scope of "influencing the eating behaviour" as recited in claims 62 and 65.

The amount of direction or guidance presented: The *in-vitro* data in the specification shows the claimed compounds have antagonistic effect on MCH-1 receptor which would result in an anorexic effect, and support the treatment of obesity. The specification does not provide any evident to treat other diseases. Thus, the enablement provided is insufficient for the scope of treamtent claimed herein.

The state of the prior art: As evident by many references cited in the specification (e.g., **Borowsky et. al.**), the antagonistic effect on MCH-1 receptor causes animals to lose weight. Thus, the state of the art seems to support only the treatment of obesity.

The relative skill of those in the art: Even with the advanced training, the skilled medicinal chemist and/or clinician would have to carry out extensive research to make an array of compounds of formula I.1, and select an effective compound from such a large Markush group for different effects allegedly related to MCH-1 receptor. Not only one has to determine the inhibitory activity on MCH-1 receptor, but also *in-vivo* activity to establish an LD_{50}, therapeutic index and pharmacokinetic profile for each compound. Given a large Markush group of the claimed formula I.1, such a task would require a tremendous amount of effort, time and resource.

The predictability or unpredictability of the art & The quantity of experimentation necessary: The pharmaceutical art has been known for its unpredictability due to various conflicting pathways, or biological factors that are sometimes genetically unique to individuals. In the instant case, the specification fails to provide biological data for using the claimed

compounds in various methods of treatment. Thus, with the large Markush group of formula I.1, without the guidance for efficacy to treat other diseases, undue experimentation is necessary for selecting an effective compound from such a big Markush group.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 45-59 and 61-68 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

a. Claims 45 and dependent claims thereon recite many limitations begin with the phrase "*while the above mentioned...*" which sounds like a proviso. If they are not a proviso, applicant is suggested to use the word "wherein" in place of "while".

b. Claims 62 and 65 recite limitation of "*influencing the eating behavior*" which encompasses diseases of conflicting symptoms such as obesity vs. anorexia.

c. Claim 68 recites the limitation of "*preventing and/or treating symptoms and/or diseases which are caused by MCH...*" which covers a lot of diseases known and unknown currently. Defining a disease(s) by its (their) underlying cause renders the scope of intended uses indeterminate since the claim language may read on diseases not yet known to be caused by or affected by such action or in ways not yet understood.

Additionally, determining whether a given disease responds or not to MCH-1 receptor antagonism involves much experimentation since a negative response from one patient does not mean the drug isnt useful as no drug has 100% effectiveness. Thus what "success rate" determines if a particular inhibitor is effective and how many patients (and dosage regimens) need to be tested? The test for determining compliance with 35 USC 112, par.two is whether applicants have clearly defined "their" invention not what may be discovered by future research as this type of claim language clearly requires.

Claim Objections

3. Claim 60 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Also Claim 60 recites species that are outside of the elected group. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

References cited on PTO-892

4. References cited on PTO-892 (Angell et. al. and Aston et. al.) show state of the art only. Because of their late effective filing date, they are not competent prior arts.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 571-272-0676. The examiner can normally be reached on M, T and Th (9:00-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Tamthom N. Truong/

Tamthom N. Truong
Examiner
Art Unit 1624

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11-10-07

JAMES O. WILSON
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